



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification<sup>6</sup> : <b>A61F 5/44</b></p>	<p><b>A1</b></p>	<p>(11) International Publication Number: <b>WO 99/30652</b></p> <p>(43) International Publication Date: 24 June 1999 (24.06.99)</p>
<p>(21) International Application Number: PCT/SE98/02317</p> <p>(22) International Filing Date: 15 December 1998 (15.12.98)</p> <p>(30) Priority Data: 9704712-0 17 December 1997 (17.12.97) SE</p> <p>(71) Applicant (for all designated States except US): ASTRA AKTIEBOLAG [SE/SE]; S-151 85 Södertälje (SE).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): DVÄRSÄTER, Gudmund [SE/SE]; Astra Tech AB, P.O. Box 14, S-431 21 Mölndal (SE).</p> <p>(74) Agent: ASTRA AKTIEBOLAG; Intellectual Property, Patents, S-151 85 Södertälje (SE).</p>		<p>(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: MEDICAL DEVICE</p> <div data-bbox="337 1129 1291 1747"> </div> <p>(57) Abstract</p> <p>Rectal insertion device (1) for treating disorders of the digestive tract of a human or animal body such as colic comprising an elongate shaft (3) which is insertable into the anal canal of the human or animal body and a receptacle (12) for collecting faeces discharged when the elongate shaft is inserted into the anal canal.</p>		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

## MEDICAL DEVICE

### Field of the Invention

5 The present invention relates to a rectal insertion device for treating disorders of the digestive tract in human or animal bodies such as colic, including infantile colic, haemorrhoids, constipation, gas, piles and the like.

### Background of the Invention

10

A rectal insertion device for treating colic, constipation and gastrointestinal gases is disclosed in International patent application publication WO94/20059. The rectal insertion device takes the form of a solid rod of a diameter small enough to fit into the anal canal but wide enough to sufficiently stimulate the sphincter  
15 muscles without completely filling the anal canal. The device is used to treat colic, constipation and gastrointestinal gases by moving the rod back and forth in the anal canal to stimulate the sphincter muscles until gastrointestinal gases are released over the outer surface of the rod. A transversely extending plate is provided on the rod between the proximal and distal ends to delimit insertion of  
20 the rod into the anal canal and also to serve as a handle. To assist insertion of the rod it is suggested that the rod be lubricated immediately prior to use with a lubricant such as glycerine or petroleum jelly.

US patent Nos. 4263914, 1042624 and 1547127 also make known rectal insertion  
25 devices in the form of rods for treating rectal diseases such as haemorrhoids and piles. In these devices the rods are provided with a central lumen which extends between an opening in the tip at the distal end of the rod and an opening in the proximal end of the rod. It is also suggested for some of these devices that insertion into the anal canal would be facilitated by lubricating the outer surface of  
30 the rod immediately beforehand, for example with "Vaseline".

A problem with the hitherto proposed devices is that no provision is made for capturing the faeces discharged through the anal canal as a result of their application. The aim of the present invention is to address this problem.

5

### Disclosure of the Invention

According to the present invention there is provided a rectal insertion device for treating disorders of the digestive tract in a human or animal body comprising an  
10 elongate shaft which is insertable into the anal canal of the human or animal body and a receptacle for collecting faeces discharged from the anal canal when the elongate shaft is inserted into the anal canal.

In an embodiment of the invention such as the one hereinafter to be described the  
15 receptacle is coupled to the proximal end of the elongate shaft.

In an embodiment of the invention such as the one hereinafter to be described the shaft is provided with a lumen which extends between a proximal opening in the proximal end of the elongate shaft and a distal opening in the distal end of the  
20 elongate shaft and the receptacle communicates with the proximal opening of the lumen. The receptacle may be made of a material which is gas permeable thereby to allow gastrointestinal gases discharged through the lumen of the device to pass through the receptacle.

25 In an embodiment of the invention such as the one hereinafter to be described the rectal insertion device is provided with means for controlling the degree of insertion of the elongate shaft into the anal canal, for example a transversely extending plate-like element mounted on the shaft.

In an embodiment of the invention such as the one hereinafter to be described the elongate shaft is preformed with a friction-reducing coating on the outer surface thereof. This negates the requirement with the previous devices to lubricate the outer surface with a jelly or the like immediately prior to use. The friction-reducing coating may be a hydrophilic coating which has a reduced friction when wetted, for example a coating formed from polyvinyl pyrrolidone.

The elongate shaft of the rectal insertion device may be presented by a urethral drainage catheter and the receptacle by a urine collection bag.

In an embodiment of the invention the elongate shaft of the rectal insertion device is adapted for insertion into the anal canal of a human infant body whereby disorders of the digestive tract of the human infant body such as infantile colic are treatable.

According to the present invention there is further provided a kit for the treatment of disorders of the digestive tract in a human or animal body comprising a structure which presents an elongate shaft which is insertable into the anal canal of the human or animal body and a receptacle which is adapted to be coupled to the structure for collecting discharged faeces when the elongate shaft is inserted into the anal canal.

#### Description of Exemplary Embodiment of the Invention

By way of example, an embodiment of the invention will now be described with reference to the accompanying Figure which shows in cross-section a rectal insertion device 1 for treating digestive disorders such as colic in human patients comprising a thermoplastic elongate shaft 3 having a closed tip 5 at the distal end thereof and a lumen 6 which extends between a distal opening 7 in the tip 5 and a proximal opening 9 in the proximal end of the shaft 3. The diameter of the shaft

will typically be in the range of about 3-6mm when for use with infants and in the range of about 6-15mm when for use with adults.

In use, the tip 5 of the shaft 3 is positioned just past the external sphincter muscles  
5 at the entry point to the anal canal thereby enabling the sphincter muscles to be stimulated if need be and gastrointestinal gases and faeces to be discharged through the lumen 6. The insertable length of the shaft 3 for adults would ordinarily be anywhere up to 20mm and in the range of about 5-10mm for infants. With this in mind, the device 1 further comprises a plate 11 mounted on the shaft 3  
10 to limit the degree of insertion of the shaft 3 into the anal canal to prevent damage to the rectum and large intestine.

To facilitate insertion of the shaft at least a substantial portion of the outer surface of the insertable length of the shaft 3 is preformed with a hydrophilic outer surface  
15 coating, for example a polyvinyl pyrrolidone-based hydrophilic outer surface coating applied in accordance with one of the methods disclosed in European patent Nos. 0093093 and 0217771.

For greater efficiency of release of gastrointestinal gases and faeces the distal  
20 portion of the insertable length of the shaft 3 may be provided with further openings which communicate with the lumen 6.

While the provision of the plate 11 is preferable it is of course entirely optional. Other means of controlling the extent of insertion of the shaft 3 could be provided,  
25 for instance markings on the shaft 3, or dispensed with completely. If the plate 11 is dispensed with then the shaft 3 could simply be a "converted" surface coated urethral drainage catheter, for instance the hydrophilic surface coated urinary catheter marketed by Astra Tech AB, Mölndal, Sweden under the trade mark LoFric®. Of course, the shaft 3 of the device 1 shown could be formed by such a  
30 urethral drainage catheter with the plate 11 being added thereto.

Attached to the proximal end of the elongate shaft 3 is a bag 12 for collecting faeces discharged through the lumen 6. The proximal end of the shaft 3 is flared so as to form a mechanical seal with the opening of the bag 12 as shown. The shaft 3 (with or without the plate 11) could be packaged inside the bag 12 with an opening being made in the bag just prior to use for the shaft 3 to be pushed through until the mechanical seal is formed. Where the plate 11 is included, the shaft 3 would be pushed through the opening in the bag 12 until the plate 11 forms a seal with the opening, that is to say, the plate 11 would remain in the bag 12.

This type of arrangement is already known from International patent application publication No. WO97/26937 and UK patent application publication No. 2284764 for combining a urethral drainage catheter with a urine collection bag for collecting urine from the bladder and the contents of these two publications relating to this feature are incorporated herein by reference.

**CLAIMS:**

1. A rectal insertion device (1) for treating disorders of the digestive tract of a human or animal body comprising an elongate shaft (3) which is insertable into  
5 the anal canal of the human or animal body characterised in that the rectal insertion device (1) further comprises a receptacle (12) for collecting faeces discharged when the elongate shaft is inserted into the anal canal.
2. A rectal insertion device (1) according to claim 1, characterised in that the  
10 receptacle (12) is coupled to the proximal end of the elongate shaft (3).
3. A rectal insertion device (1) according to claim 1 or 2, characterised in that the elongate shaft (3) is provided with a lumen (6) which extends between a distal opening (7) in the distal end of the elongate shaft (3) and a proximal opening (9) in  
15 the proximal end of the elongate shaft (3) and that the receptacle (12) communicates with the proximal opening (9) of the lumen (6).
4. A rectal insertion device (1) according to claim 1, 2 or 3, characterised in that the elongate shaft (3) is preformed with a friction-reducing coating on the  
20 outer surface thereof.
5. A rectal insertion device (1) according to claim 4, characterised in that the friction-reducing coating is a hydrophilic coating which has a reduced friction when wetted.  
25
6. A rectal insertion device (1) according to any one of the preceding claims, characterised in that insertion control means (11) are provided for controlling the degree of insertion of the elongate shaft (3) into the anal canal.



7. A rectal insertion device (1) according to claim 6, characterised in that the insertion control means comprises a transversely extending plate-like element (11) mounted on the shaft.

5 8. A rectal insertion device (1) according to any one of the preceding claims, characterised in that the elongate shaft (3) is adapted for insertion into the anal canal of a human infant body.

9. A kit for the treatment of disorders of the digestive tract in a human or  
10 animal body comprising a structure which presents an elongate shaft (3) which is insertable into the anal canal of the human or animal body and a receptacle (12) which is adapted to be coupled to the structure for collecting discharged faeces when the elongate shaft (3) is inserted into the anal canal.

15 10. A rectal insertion device (1) for treating disorders of the digestive tract of a human or animal body substantially as hereinbefore described with reference to the accompanying drawing.

1/1

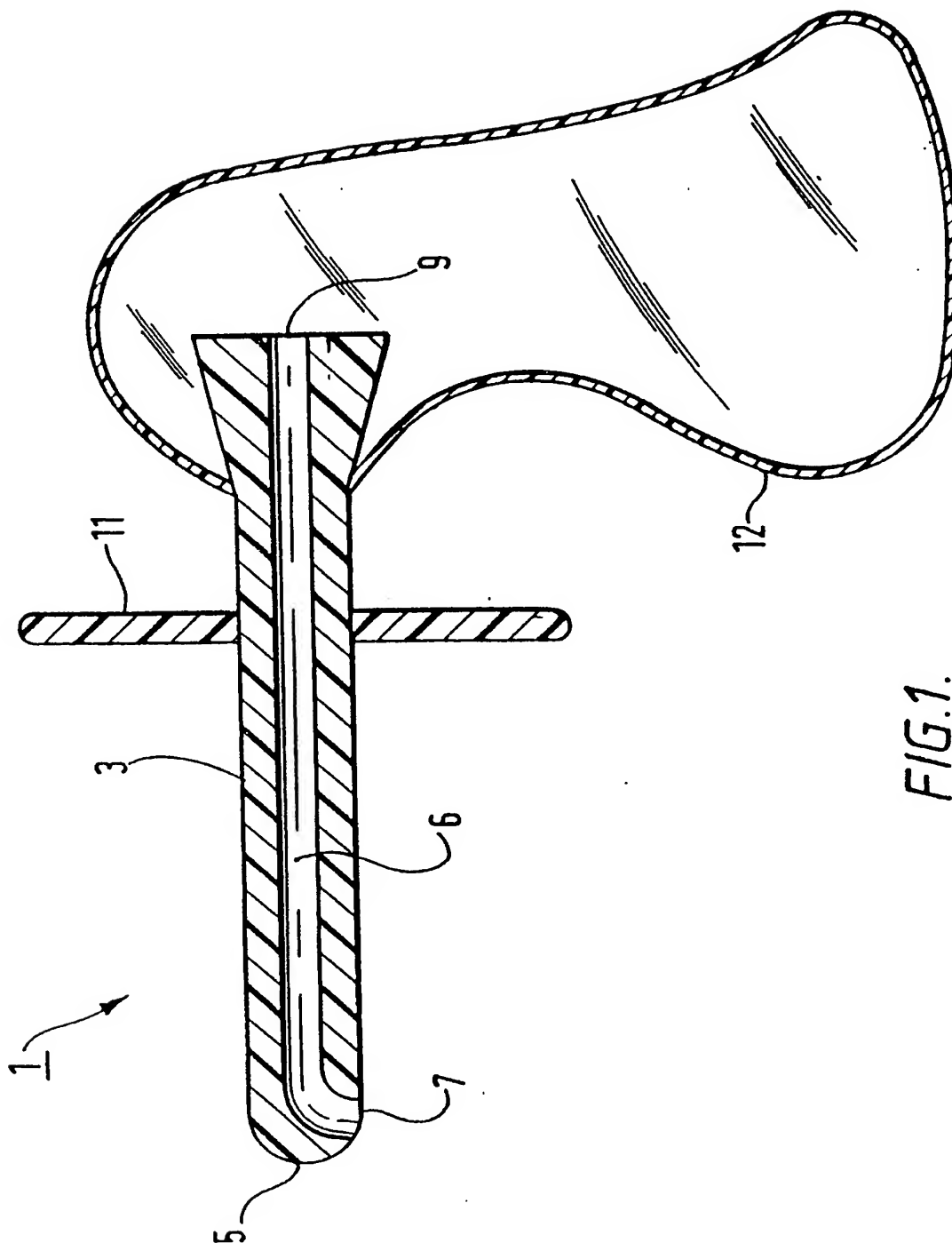


FIG. 1.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 98/02317

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 5/44

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4137918 A (BOGERT), 6 February 1979 (06.02.79), figures 1-5, claims 1-3	1-3,6-10
Y	--	4-5
Y	US 4585666 A (LAMBERT), 29 April 1986 (29.04.86), column 1, line 14 - line 34, claims 1-5	4-5
A	US 2291191 A (W.T SCUDDER, JR), 28 July 1942 (28.07.42), figures 1-2, claims 1-2	1-10
	-- -----	

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

9 April 1999

Date of mailing of the international search report

14 -04- 1999

Name and mailing address of the ISA/  
 Swedish Patent Office  
 Box 5055, S-102 42 STOCKHOLM  
 Facsimile No. +46 8 666 02 86

Authorized officer

Agneta Ånggård  
 Telephone No. +46 8 782 25 00

# INTERNATIONAL SEARCH REPORT

Information on patent family members

02/03/99

International application No.

PCT/SE 98/02317

Patent document cited in search report			Publication date	Patent family member(s)	Publication date
US	4137918	A	06/02/79	NONE	
US	4585666	A	29/04/86	AT 18568 T AU 556351 B AU 1326783 A CA 1215597 A DK 159972 B,C DK 170983 A EP 0093093 A,B SE 0093093 T3 FI 73701 B,C FI 831339 A GB 2122510 A,B HK 92186 A IE 54204 B JP 1670911 C JP 3035990 B JP 58193767 A SE 430695 B,C SE 8202523 A US 4666437 A	15/03/86 30/10/86 27/10/83 23/12/86 07/01/91 23/10/83 02/11/83 31/07/87 23/10/83 18/01/84 12/12/86 19/07/89 12/06/92 30/05/91 11/11/83 05/12/83 23/10/83 19/05/87
US	2291191	A	28/07/42	NONE	